

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

NEPTUNE TECHNOLOGIES &
BIORESSOURCES, INC., and
L'UNIVERSITÉ DE SHERBROOKE,

Plaintiffs,

v.

AKER BIOMARINE ASA,
AKER BIOMARINE ANTARCTIC AS,
JEDWARDS INTERNATIONAL, INC., and
VIRGIN ANTARCTIC LLC,

Defendants.

C.A. No. 1:09-cv-11946-MLW

PLAINTIFFS' MEMORANDUM IN
OPPOSITION TO AKBM
ANTARCTIC'S RENEWED MOTION
FOR SUMMARY JUDGMENT OF
NON-INFRINGEMENT

FILED UNDER SEAL

AKER BIOMARINE ANTARCTIC AS,
JEDWARDS INTERNATIONAL, INC., and
VIRGIN ANTARCTIC LLC,

Counterclaim Plaintiffs,

v.

NEPTUNE TECHNOLOGIES &
BIORESSOURCES, INC., and
L'UNIVERSITÉ DE SHERBROOKE,

Counterclaim Defendants.

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GRANTED ON 1/10/2011

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO AKBM ANTARCTIC'S
RENEWED MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT**

I. Introduction

Consistent with Defendants' approach to date, Defendants' latest Motion for Summary Judgment ("Aker's Motion") ignores concrete evidence established by Plaintiffs that creates a genuine issue of material fact regarding Defendants' infringement of U.S. Patent No. 6,800,299

(the “299 Patent”). From the outset of this case, the evidence has been conflicting: on the one hand, Defendants Aker BioMarine ASA, Aker BioMarine Antarctic AS, Jedwards, International, Inc., and Virgin Antarctic LLP (collectively, “Aker” or “Defendants”) have sought to rely on documents purportedly describing the process used to extract Superba Krill Oil which, admittedly, do not reference the use of acetone; on the other hand, beginning in late 2008 and continuing until as recently as December 2010, Plaintiffs Neptune Technologies & Bioressources, Inc. and L’Universite de Sherbrooke (collectively, “Neptune” or “Plaintiffs”) have [REDACTED] tested samples of Superba Krill Oil and, [REDACTED] have found them to contain acetone. Although Aker attempts to criticize the reliability of this evidence and contend that such circumstantial evidence is insufficient to prove infringement, it has failed to offer either any test results of their own showing that acetone is not present in Superba Krill Oil or any credible explanation for why acetone would be present in the finished product if it is not added during processing. Under these circumstances, there can be little doubt that at least a genuine issue of material fact exists as to whether or not Aker has used and is continuing to use the accused process.

Even apart from the evidence of the infringing use of acetone and ethanol provided by Neptune’s testing, it is undisputed that, [REDACTED]

[REDACTED]

[REDACTED] This undisputed evidence supports a finding of infringement of at least one of the asserted claims under the doctrine of equivalents. Aker attempts to avoid this undisputed evidence through an unduly narrow interpretation of the claim language that is not supported by any evidence in the claim language, the specification, or the prosecution history. As a result, a genuine issue of material

fact exists as to whether [REDACTED] infringes claim 13 of the '299 patent under the doctrine of equivalents.

Recognizing the challenges posed its own documents showing [REDACTED] [REDACTED] and Neptune's unrebutted and unexplained test data showing the presence of acetone in Superba Krill Oil, Aker has invented an additional non-infringement argument – that its process does not produce a “total lipid fraction.” However, that argument also relies on a strained construction of the claim language that departs dramatically from the plain and ordinary meaning of the claim language, [REDACTED] [REDACTED] [REDACTED] this basis for summary judgment also must fail.

Finally, to the extent the Court concludes that the circumstantial evidence of infringement provided by Neptune's test data is insufficient to create a genuine issue of material fact, it should permit Neptune to obtain – and order Aker to produce - certain key documents and things that Plaintiffs requested during discovery, but which Aker consistently refused to provide. The missing information may be highly relevant to determining whether acetone is present during the extraction of the accused products and/or why it is present in the finished product that Neptune has tested, and thus may enable the parties once and for all to reconcile the conflicting evidence relating to the presence of acetone in Aker's products.

In view of the existence of disputes of material fact, Neptune respectfully request that Aker's Motion be denied.

II. Factual Background

A. U.S. Patent No. 6,800,299

The asserted patent is U.S. Patent No. 6,800,299 (the “’299 Patent”), which describes novel and improved methods of extracting beneficial oils (also called “lipids”) from small marine animals. *See* Plaintiffs’ Statement Pursuant To Local Rule 56.1, Statement of Additional Facts As To Which There Exists A Genuine Issue To Be Tried (“SAF”) at ¶ 1. These oils, which are rich in omega-3 fatty acids, can help to promote health and prevent disease when taken as dietary supplements. *Id.* at ¶ 2. Prior to the discovery of the methods claimed in the ‘299 patent, various solvents were used to extract oils from aquatic animals. *Id.* at ¶ 3. However, the prior art methods suffered from many drawbacks - some involved highly toxic chemicals, and others failed to efficiently extract certain beneficial ingredients into the product oil. *Id.* at ¶ 4. The ‘299 Patent identified an improved method of extracting lipid fractions with solvents that were highly effective in producing high quality oils, but which lacked the toxicity associated with many earlier solvent systems. *Id.* at ¶ 5.

B. Representative Claims

The ‘299 patent is generally directed to the extraction of oils using one or two step extraction procedures. *Id.* at ¶ 6. Claim 1 is representative of the two step extraction processes, and involves first performing an extraction with a “ketone solvent” (*e.g.*, acetone) and then performing a second extraction on the remaining solids with either an “alcohol” (*e.g.*, ethanol), or an “ester of acetic acid” (*e.g.*, ethyl acetate):

1. A method for extracting total lipid fractions from marine and aquatic animal material, said method comprising the steps of:
 - (a) placing marine and aquatic animal material in a ketone solvent to achieve extraction of the soluble lipid fraction from said marine and aquatic animal material;
 - (b) separating the liquid and solid contents;

- (c) recovering a first total lipid rich fraction from the liquid contents of b) by evaporation of the solvent present in the liquid contents;
- (d) placing said solid contents in an organic solvent selected from the group of solvents consisting of alcohol and esters of acetic acid to achieve extraction of the remaining soluble total lipid fraction from said marine and aquatic animal material;
- (e) separating the liquid and solid contents;
- (f) recovering a second total lipid rich fraction by evaporation of the solvent from the liquid contents of e); and
- (g) recovering the solid contents.

SAF at ¶ 7; Ex. A, '299 Patent, claim 1.¹

Claim 13, which is illustrative of a one step extraction process, involves an extraction done with a mixture of acetone (a ketone solvent) and ethanol (an alcohol):

13. A method for extracting a total lipid fraction from a marine and aquatic animal material selected from zooplankton and fish, said method comprising the steps of:
- (a) placing said animal material in a solvent mixture comprising acetone and ethanol to achieve an extraction of the soluble lipid fraction from said marine and aquatic animal material;
 - (b) separating the liquid and solid contents; and
 - (c) recovering a lipid rich fraction from the liquid contents by evaporation of the solvents present in the liquid contents, whereby a total lipid fraction is obtained.

SAF at ¶ 8; Ex. A, '299 Patent, claim 13.

C. Accused Processes

Aker manufactures and, through its distributors, including Jedwards International, Inc. and Virgin Antarctic LLC, sells Superba Krill Oil throughout the United States. SAF at ¶ 9. In some cases, the oil is encapsulated and sold in capsule form. *Id.* Krill is a generic term for deepwater marine planktonic crustacean species, which are akin to miniature shrimp, and krill oil is extracted from krill. *Id.* at ¶ 10.

¹ Unless otherwise noted, all exhibits referenced herein are the Exhibits to the Declaration of Jason H. Liss, Esq. in Support of Plaintiffs' Opposition to AKBM Antarctic's Renewed Motion for Summary Judgment of Non-Infringement ("Liss Decl.").

Aker harvests krill in the Antarctic, [REDACTED]

[REDACTED]

[REDACTED] It then transports the krill meal to a third party company called Naturex, which in turn extracts oil from the krill meal and further processes it in order to produce Superba Krill Oil. *Id.* at 15. The Naturex facility in Avignon, France performed the extraction and processing for Aker [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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SAF at ¶ 39.

- (c) Finally, most recently, Neptune obtained additional samples of Schiff's MegaRed product, containing Superba Krill Oil and sent them for testing to another independent laboratory, Laboratoire Garmen in Quebec, Canada. The tests were conducted between November 8 and December 10, 2010, and used gas chromatography. The results showed acetone at levels ranging from 7.6 ppm to 12.3 ppm. SAF at ¶¶ 40-42.

Aker has produced no evidence of any testing that it, or anyone on its behalf, has performed to determine the amount of acetone in its products. Accordingly, the only evidence in the record is that described above, which demonstrates that, to this day, Superba Krill Oil contains acetone.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The only relevant testimony is that of Neptune's expert, Dr. Moore, who has opined that, although such explanations might explain why *some* acetone is present in the oil, the amounts of acetone that might result from such explanations are significantly lower than what was found in any of Neptune's testing. *Id.* at ¶

46-48. As a result, such assertions do not suffice to explain the acetone present in the samples tested, leading to the conclusion that such acetone was added during the processing of the oil. *Id.*

D. In Spite of Plaintiffs' Diligent Discovery Efforts, Defendants Still Have Failed to Produce Critical Information Relevant to the Issue of Infringement

After plaintiffs filed their Complaint in November of 2009, Aker prematurely filed a motion for summary judgment, before discovery had even begun. (*See* Dkt. Nos. 30-36, AKBM Antarctic's Motion for Summary Judgment of Non-infringement.) The Court denied that motion and granted Plaintiffs' motion under Rule 56(f), agreeing that Plaintiffs were entitled to a period of discovery. (*See* Dkt. No. 77, Order denying summary judgment of non-infringement; Dkt. No. 95, redacted transcript of hearing on motion for summary judgment of non-infringement.) The Court bifurcated the proceedings, ordering that the first phase be limited to issues of infringement. *See* Dkt. No. 93, June 25, 2010 Scheduling Order.

Discovery commenced following the entry of the June 25, 2010 Scheduling Order. *Id.* During the course of discovery, Plaintiffs served Defendant with 32 requests for documents and things and 12 interrogatories. (*See* Ex. M, Plaintiffs' First Set of Interrogatories to Defendants, Plaintiffs' Second Set of Interrogatories to Defendants and Ex. N, Plaintiffs' First Set of Requests for Documents and Things, Plaintiffs First Amended Set of Requests for Documents and Things.) Plaintiffs also noticed four depositions of fact witnesses, the maximum number allowed by the Court – a Rule 30(b)(6) deposition of Aker, two individual depositions of Aker employees, and a Rule 30(b)(6) deposition of Naturex. (*See* Ex. O, Notices of Deposition to Aker, Naturex, S. Holm, and A. Gustavsen.) During the depositions of Aker witnesses, it became apparent from testimony that certain relevant documents and things had not been produced by Aker, even though they were clearly responsive to Plaintiffs' document requests. Specifically:

- Plaintiffs had requested samples “of each raw material/substance identified in [Aker’s] response to Plaintiffs’ Interrogatory Nos. 3 and 4 and/or in documents responsive to Request Nos. 5 and 6, *in the state in which the material is used in the manufacture* of an Aker Product.” SAF at ¶ 49. However, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] both key samples to allow Plaintiffs to test whether acetone is present during the extraction process, which would contradict potentially Aker’s assertion that it uses only ethanol to extract krill oil.
- In addition, Plaintiffs had requested all documents concerning the manufacture of Aker’s krill oil products, including all processes used, all raw materials and/or substances used in such processes, and all tests and analyses of the raw materials or the products – whether the processing occurred on a ship or in a manufacturing facility. *Id.* at ¶ 52. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- Finally, Plaintiffs had requested “all documents concerning studies, testing, and/or analyses of the composition of (i) Aker Products; (ii) raw materials ...and/or (iii) substances” used in the manufacture of the krill oil products. SAF at ¶ 56.

[REDACTED]

[REDACTED]

[REDACTED] Aker failed to produce the reports of such analyses even though such reports might show: (1) the presence of acetone (and, if present, the amount) in either the krill meal before processing or the extracted oil; and (2) the lipid content of the extracted oil. *Id.* at ¶ 58.

Plaintiffs sought these items from Aker following the depositions, but Aker refused to produce them. The depositions took place in Norway at the end of August 2010. (*See* Ex. E, Holm Dep.; Ex. G, Gustavsen Dep.) On September 17, 2010, Plaintiffs sent Defendants a letter calling to their attention these and various other deficiencies and asking that they either indicate that they will produce the materials, or otherwise meet and confer regarding the missing items within three business days. (*See* Ex. P, September 17, 2010 Letter from S. Abdullah to A. Hollis.) Defendants never responded. Finally, on Friday, September 24, in response to Defendants’ request the night before to have a conference regarding other discovery issues, the parties held a telephone conference during which they discussed the deficiencies in Defendants’

production. (*See* Ex. Q, September 23, 2010 E-mail Correspondence between S. Abdullah and A. Hollis and Ex. R, September 24, 2010 Letter from S. Abdullah to A. Hollis Regarding Discovery.) During the conference, Defendants categorically refused to produce any of the documents or samples identified above. (*See* Ex. R, September 24, 2010 Letter from S. Abdullah to A. Hollis Regarding Discovery.) Plaintiffs immediately informed Defendants of their intention to file a motion to compel and filed on the next business day. (*See* Ex. R, September 24, 2010 Letter from S. Abdullah to A. Hollis Regarding Discovery; Dkt. No. 118, Plaintiffs' Motion to Compel dated September 27, 2010.) The motion was heard, along with other two motions filed by Defendants, on October 13, 2010.⁵ (*See* Ex. S, Transcript of Hearing before Judge Wolf, October 13, 2010.) As of today, Aker has refused to produce these items, *despite* the Court's admonition that it should consider producing the documents and samples to facilitate a resolution of the case and to avoid having any further summary judgment motion defeated because of failure to provide relevant documents and things. (*Id.* at 47:5-13; 53:6-9.)

Aker attempts to paint a misleading portrait of failure by Neptune to pursue discovery diligently. However, the actual facts demonstrate that it was Aker's obstructionist tactics that prevented Neptune from obtaining additional information relevant to the issue of infringement. First, with respect to the Rule 30(b)(6) deposition of Naturex, Aker prevented Neptune from conducting that deposition because it refused to produce the witness in a location where such a deposition could legally proceed. Throughout the course of discovery, Aker represented to Plaintiffs that it was cooperating with Naturex and would be willing to produce a witness from that company for a deposition. (*See* Ex. T, Letter from S. Abdullah to A. Hollis dated August 13, 2010.) In response to Plaintiffs' Rule 30(b)(6) deposition notice to Naturex, however, Aker

⁵ The Court did not grant the motion to compel, but noted that filing a Rule 56(f) request in connection with plaintiffs' opposition to Defendants' motion for summary judgment might be appropriate. (*See* Ex. S, Transcript of Hearing before Judge Wolf, October 13, 2010, 35:2-15, 46:12-21.)

responded that a Naturex witness would be made available for deposition in France. (*See* Ex. U, Letter from S. Abdullah to A. Hollis dated September 7, 2010.) However, as Plaintiffs advised Aker, French law prohibits the taking of U.S.-style depositions in France. *Id.* Accordingly, Plaintiffs suggested the alternative of having the deposition in a European country in close proximity to France, such as Italy. (*See* Ex. U, Letter from S. Abdullah to A. Hollis dated September 7, 2010.) Aker refused, and thus effectively precluded Plaintiffs from obtaining testimony from Naturex. (*See* Ex. P, Letter from S. Abdullah to A. Hollis dated September 17, 2010.)

Second, in granting Plaintiffs' first Rule 56(f) motion, the Court ordered Aker to make the Naturex manufacturing facility where Superba Krill Oil was manufactured available to Plaintiffs for inspection. (*See* Dkt. No. 93, June 25, 2010 Scheduling Order, ¶ 5.) After document production was substantially complete and Plaintiffs had more information regarding Aker's manufacture of krill oil, Plaintiffs formally requested the opportunity to proceed with such an inspection. (*See* Ex. V, Letter from S. Abdullah to A. Hollis dated August 2, 2010.) At that time, for the first time, counsel for Aker informed Plaintiffs that Aker recently had moved the processing of Superba Krill Oil from Naturex's facility in Avignon, France [REDACTED]

[REDACTED] in light of the fact that the products that Neptune had tested would have originated from the Avignon facility, Neptune determined that it would be most useful to inspect the Avignon plant; the source of the evidence of infringement. When counsel for Plaintiffs inquired regarding the Avignon plant, counsel for Aker initially represented that there was nothing relevant there to inspect. *Id.* However, a few weeks later, Aker stated it would allow a limited inspection of the Avignon plant, and invited Plaintiffs to describe what

they wished to inspect. (*See* Ex. W, Letter from A. Hollis to S. Abdullah dated August 4, 2010, p. 3.) Plaintiffs complied with this request, sending multiple letters detailing what was to be inspected. (*See* Ex. T, Letter from S. Abdullah to A. Hollis dated August 13, 2010; Ex. U, Letter from S. Abdullah to A. Hollis dated September 7, 2010.) Aker rejected much of Plaintiffs' proposal, and instead sought to impose numerous restrictions on the inspection. For example, Plaintiffs proposed an inspection of tank farms or other large containers [REDACTED]. (*See* Ex. U, Letter from S. Abdullah to A. Hollis dated September 7, 2010.) Plaintiffs also sought to inspect Naturex's quality control lab facilities and operations to determine if Naturex has the capability to monitor quality and amounts of ketone solvents. *Id.* Defendants declared that these facilities (among others) were irrelevant to infringement and that Naturex would allow only a limited inspection. (*See* Ex. X, Letter from A. Hollis dated September 10, 2010.) After considering the restrictions imposed by Aker, the fact that Naturex only produced 14 pages of documents (on September 13, less than a week before the close of fact discovery), and the impossibility of compelling a more robust inspection under French law, Plaintiffs determined that the costs to both parties of conducting the limited inspection being permitted by Aker outweighed any minimal information they would be able to obtain. Therefore, Aker's refusal to cooperate with discovery once again hindered Plaintiffs' attempts to assess the truthfulness of Aker's representations regarding its manufacturing process.

Discovery closed on September 17, 2010. (*See* Dkt No. 113, Order of August 24, 2010.) The parties exchanged expert reports, and depositions of the two experts were conducted in November of 2010. Following the close of expert discovery, Aker filed the instant Motion.

III. Argument

A. **Summary Judgment Must Be Denied When Genuine Issues Of Material Fact Are Present**

Infringement of a claim either literally or under the doctrine of equivalents is a question of fact. *IMS Tech., Inc. v. Hass Automation, Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000). When considering a motion for summary judgment, the court draws all reasonable inferences in favor of the nonmoving party. *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1318 (Fed. Cir. 2004). Summary judgment of non-infringement is only appropriate if the pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits, show that there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Where, as here, material facts are in dispute or the law requires, summary judgment should be denied. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-323 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-55 (1986).

B. **An Issue of Material Fact Exists As to Whether [REDACTED] Infringes Claim 13 Under the Doctrine Of Equivalents**

1. [REDACTED] Performs the Same Function, in the Same Way, and with the Same Result as a Mixture of Acetone and Ethanol

[REDACTED] a mixture of ethanol and acetone and [REDACTED] would perform similar functions in a lipid extraction process. *Id.* at ¶ 62. In addition, [REDACTED] would function in substantially the same way in such a solvent mixture - by preferentially interacting with *similar* lipidic molecules and drawing them into the solvent mixture. *Id.* at ¶ 63.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211,1218 (Fed. Cir. 1995) (affirming district court finding of infringement under doctrine of equivalents where accused “membranes had substantially the same chemical and physical structure, performed the same function in the same way, and achieved the same result, as [the] claimed membranes”).

2. Aker’s Proposed Construction of Limitation (a) of Claim 13 Lacks Support.

Aker attempts to avoid infringement by improperly introducing a limitation in claim 13 without any basis for that limitation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, this argument misses important facts and is based on a flawed analysis. First, claim 13 does not use the term “ketone solvent” – rather, it refers to “a solvent mixture comprising acetone and ethanol.” Thus, the question, under a doctrine of equivalents analysis, is whether [REDACTED] [REDACTED] would function in the same way as a mixture of acetone and ethanol.

Second, nowhere in the claim language, the specification, or the prosecution history is there any support for Aker’s assertion that “placing said animal material in a solvent mixture comprising acetone and ethanol to achieve an extraction of the soluble lipid fraction from said

marine and aquatic animal material” means “placing marine and aquatic animal material in a mixture comprising acetone and ethanol wherein each of the acetone and ethanol is present in an amount sufficient for the mixture to dissolve and extract a total lipid fraction from the marine and aquatic animal material.” [REDACTED]

[REDACTED]

[REDACTED] Nowhere in claim 13 is there a requirement of a certain ratio of acetone to ethanol. (*Id.* at 206:5-12.) All that the claim requires is for the *mixture* of acetone and ethanol to achieve an extraction of the soluble lipid fraction. (*Id.* at 206:13-25.) There is no basis in the specification or the prosecution history to impose the further limitation on the claim proposed by Aker.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3. Claim 13 Does Not Disclaim [REDACTED]

Aker's assertion that ketones other than acetone are disclaimed by the language of claim 13 is incorrect as a matter of law. As an initial matter, courts have recognized that "[t]he use of chemical substitutes for patented ingredients that are from the same family of chemicals may constitute infringement under the doctrine of equivalents." *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F.Supp.2d 265, 291 (D. Md. 1998) (citing *Graver Tank*, 339 U.S. at 607-08, 70 S.Ct. 854; *Saes Getters S.P.A. v. Ergenics, Inc.*, 17 U.S.P.Q.2d 1581, 1589 (D.N.J.), *aff'd*, 914 F.2d 270 (Fed.Cir.1990). Aker's distinction serves only to demonstrate that there can be no *literal* infringement of claim 13 if the solvent mixture does not include acetone and ethanol. It does not preclude a finding of infringement of claim 13 in this case under the doctrine of equivalents.

Indeed, Aker does not cite to any evidence of disclaimer – it merely points to the fact that “acetone” is the term used in the claim rather than “ketone solvent.” Nothing in the specification or prosecution history, however, indicates that the inventors explicitly intended to exclude any substances equivalent to acetone in claim 13. *See JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005) (“We do not import limitations into claims from examples or embodiments”); *EcoLab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1343 (Fed. Cir. 2009) (prosecution history disclaimer must be “clear and unmistakable”).

Moreover, Aker's reliance on *Tanabe Seiyaku Co. v. ITC*, 109 F.3d 726, 732 (Fed. Cir. 1997), is misplaced. In *Tanabe*, the inventor specifically defined his invention not only in the claims but also in the specification and prosecution history in terms of five specific base-solvent combinations. *See id.* at 733; *see also Glaxo Wellcome*, 32 F.Supp.2d 265, 290 (distinguishing *Tanabe* because the applicant in *Tanabe* "rejected [butanone] as a possible element to claim in the process). Here, Aker has not cited to any evidence – and there is none – of a "clear and unmistakable surrender...during prosecution." *Abraxis Bioscience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370, 1381 (Fed. Cir. 2006).

C. A Genuine Issue of Material Fact Exists As to Whether Aker Uses Acetone to Extract Krill Oil in Violation of Claim 1 of the '299 Patent

In arguing for summary judgment of non-infringement, Aker relies on manufacturing documents purporting to show that, [REDACTED], Aker has used [REDACTED] ethanol to extract Superba Krill Oil. However, Aker's reliance on those documents ignores the evidence of [REDACTED] testing of Aker's products, which has [REDACTED] shown the presence of acetone in levels that strongly suggest the addition of acetone during the processing of Superba Krill Oil. Notwithstanding the absence of any reference to acetone in the manufacturing documents produced by Aker, Neptune's test data constitutes concrete evidence that the accused processes infringe the '299 Patent and is sufficient to create a genuine issue of material fact sufficient to overcome a motion for summary judgment.⁶ *See In re Gabapentin Patent Litigation*, 503 F.3d 1254, 1260-1262 (Fed. Cir. 2007) (finding that genuine issues of material

⁶ While Neptune only has as much insight into Defendants' processes as Defendants have allowed it to have, the evidence adduced by Plaintiffs shows that acetone is being used in the process. [REDACTED]

fact existed as to infringement where patentee presented test results showing four out of five samples could meet claim limitations).

The presence of acetone in Aker's finished product is highly significant. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

During the October 13, 2010 hearing in this matter, this Court noted that evidence of the presence of acetone in Aker's product could create an issue of material fact for summary judgment. The Court stated:

...I'm going to have to look at the evidence in the light most favorable to the plaintiffs and, you know, if all the testimony is 'We don't use acetone,' but they're finding acetone and some expert tells me – or maybe no expert needs to tell me, that you wouldn't find acetone unless they were using acetone, then that might be enough to create a material disputed fact.

Ex. S, Transcript of Hearing on October 13, 2010 at 50:13-51:10. The Court's statement describes the current situation perfectly – acetone has been present [REDACTED]

[REDACTED] and plaintiffs' expert witness Dr. Moore has opined that the levels of acetone found suggest that the process Aker used to manufacture Superba Krill Oil infringes the '299 patent. SAF ¶ 70.

Moreover, Aker offers *no* explanation for the presence of acetone in its products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Aker's decision not to pursue this speculative explanation is also not surprising given the analysis of Plaintiffs' expert, Dr. Moore, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In an attempt to avoid having to explain the acetone in its products, Aker seeks to create a smoke screen by criticizing the methods by which the testing was conducted.⁸ However, Aker's efforts overlook several important facts. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Second, after initially serving a Notice of Deposition for Dr. Das, one of the individuals who conducted the testing on behalf of Neptune, Aker failed to pursue that deposition and therefore chose not to test the reliability of Dr. Das's results by obtaining his testimony regarding his methodology.

Finally, and perhaps most significantly, neither Aker nor its expert has offered any evidence of testing that *they* performed to contradict Neptune's test data. SAF ¶ 79. Aker has had at least some of Neptune's test results since the first round of summary judgment briefing in early 2010. SAF ¶ 80. It has had ample opportunity to test its own product for acetone using the methodology it considers reliable and to produce the results of that testing. It is remarkable that Aker has chosen not to undertake such testing, and it is reasonable to conclude that Aker recognized that such testing would not be helpful to its position.

⁸ Aker also baselessly accuses Neptune of withholding certain test data from the Court. In response to Aker's pre-discovery motion for summary judgment, Neptune submitted a 32-page report by Dr. Das summarizing the results of his testing showing acetone in Aker's product. Contrary to Aker's assertions, the additional test data that Aker alleges was withheld further *supported* Neptune's arguments – [REDACTED]. At no point did Neptune state that it had no other test data; nor was it required at that pre-discovery stage to present all, cumulative testing results. Aker itself had only presented a subset of documents in support of its motion. Following the denial of Aker's motion, during discovery, Neptune produced the testing data in a timely manner. As Neptune's investigation into Aker's infringement continues, Neptune has continued to perform additional tests, which it has also produced to Aker.

D. Whether Aker's Process Extracts a "Total Lipid Fraction" According to the Claims Is Disputed

Apparently recognizing that the issue of whether or not it uses or has used acetone (or another ketone solvent) to extract Superba Krill Oil is not so clear-cut as it initially represented to the Court, Aker has now invented a second non-infringement argument – namely, that the accused processes do not extract a "total lipid fraction," as required by each of the asserted claims. However, this argument – like Aker's argument with respect to claim 13 – depends on a strained construction of "total lipid fraction" that is not supported by the intrinsic evidence. Regardless of what construction the Court adopts, however, there is a factual dispute as to whether Aker's process extracts a "total lipid fraction."

1. "Total Lipid Fraction" Should Be Understood According to its Plain and Ordinary Meaning

The claims of the '299 patent require extraction of a "total lipid fraction." In the absence of any indication in the claims, the specification, or the prosecution history to the contrary, Neptune's position has been that the plain and ordinary meaning of this term is readily understood by one of ordinary skill and does not require further definition by this court.

Northern Telecom Limited, v. Samsung Electronics Co., Ltd., 215 F.3d 1281, 1295 (Fed. Cir. 2000) ("the plain and ordinary meaning of claim language controls, unless that meaning renders the claim unclear or is overcome by a special definition that appears in the intrinsic record with reasonable clarity and precision"). However, in response to Aker's attempt to narrow the meaning in a manner inconsistent with the plain and ordinary meaning of the term, Plaintiffs proposed a straightforward definition of this term reflecting its meaning to the ordinary artisan.

████████████████████ the plain and ordinary meaning of "total lipid fraction" is the "lipid portion of the naturally occurring substances from marine or aquatic animal material which are relatively insoluble in water, but soluble in organic solvents." SAF ¶¶

81-82; Ex. B, Moore Report, ¶ 30; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Aker, on the other hand, contends that the term should be defined as: “lipid fractions encompassing neutral acyl lipids including glycerides, free fatty acids and cholesterol esters; polar lipids including glycerophospholipids, glyceroglycolipids and sphingolipids; terpenoids including sterols, chlorophylls and carotenoids including astaxanthin (at least 75µg/g for krill extracts) and canthaxanthin (at least 250µg/g for krill extracts).” *See* Aker Motion.

Nowhere in the claim language is there any statement by the inventors evidencing an intent to narrow the scope of “total lipid fraction” as it is used in the claims of the ‘299 Patent.

[REDACTED] nowhere in the claims is there any limitation on what a “total lipid fraction” is, except in Claim 12. SAF ¶ 83. While Claim 1, for example, refers simply to “extracting total lipid fractions,” Claim 12 recites a “method for extracting an astaxanthin and canthaxanthin-containing total lipid fraction.” This distinction in the claim language confirms that the unmodified phrase “total lipid fraction” encompasses the full scope of the plain and ordinary meaning of that term, and that, when the inventors intended to claim a narrower scope, they explicitly indicated that the “total lipid fraction” was “astaxanthin and canthaxanthin-containing.”

Similarly, nowhere in the specification do the inventors provide a definition of “total lipid fraction.” SAF ¶ 86. Nor do the inventors ever state that for an extraction of lipids to result in a “total lipid fraction” under the ‘299 patent, it would need to produce the particular lipid profile that Defendants incorporate into their proposed construction. SAF ¶ 87. Thus, there is no

evidence that the inventors intended to be their own lexicographers and define “total lipid fraction” contrary to the plain and ordinary meaning of the phrase. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996) (to be his own lexicographer, a patentee must use a “special definition of the term [that] is clearly stated in the patent specification or file history”). The only evidence in the specification that Defendants can point to as support for their proposed construction is an example, and the accompanying figures and tables, that the report the results of the analysis of krill oil obtained from one set of experiments. [REDACTED]

[REDACTED] It is black letter law that claim language should not be limited to a particular embodiment or example in the specification. It is wholly implausible that the inventors intended to limit the scope of the claims to the particular lipid classes and amounts obtained from a single example, in light of the fact that there are multiple species of krill, and krill is a biomass with varying levels of substances present in it depending on the year, the season, the environment, and numerous other factors. SAF ¶¶ 88-89. Indeed, Aker uses a different type of krill – *E. superba* – than the *E. pacifica* that was the basis for the experiments and results reported in the ‘299 patent, and relied on by Aker as support for construing “total lipid fraction” as requiring the specific lipids in the specific amounts described in the specification. SAF ¶ 90. It would be nonsensical to require the claimed process to extract a particular type of lipid, in a particular amount if such lipids in such amounts were not naturally present in the source material in the first instance, which is effectively what Aker’s proposed construction requires. [REDACTED]

[REDACTED] In short, Aker’s attempt to limit the scope of “total lipid fraction” to the single set of data presented in the ‘299 patent is legally and factually insupportable.

Finally, contrary to Aker’s assertions, the prosecution history of the ‘299 patent also does not warrant ignoring the plain and ordinary meaning of “total lipid fraction.” Aker cites to a

paragraph in an Amendment in Response to Office Action in which the Applicants explain that “the term ‘lipid’ Refers to naturally occurring substances soluble in organic solvents, but insoluble in water.” SAF ¶ 91; Ex. AB at NEP_AKBM 61. The paragraph goes on to describe broad classes of lipids – acyl lipids and the terpenoids – and then further identifies subclasses of each. Acyl lipid types are natural acyl lipids and polar lipids. Terpenoid types are sterols, chlorophylls, and carotenoids. Aker quotes extensively from the paragraph to create its list of required lipids, but ignores the last sentence: “It is apparent throughout the present application that the term ‘total lipid’ as used therein is meant to encompass all these various *types* of lipids and that the method of the present invention is *able* to extract all these various *types* of lipids.” (SAF ¶¶ 92-93 (emphasis added).) Nothing in this sentence indicates that specific, named lipids are required to be present, or that any lipid be present in a particular concentration.⁹ Moreover, the last sentence confirms Neptune’s position that for a method to extract a “total lipid fraction” as required by the ‘299 patent claims, it need only extract all the lipids that are *able* to be extracted – *i.e.*, those that are naturally present. See SAF ¶ 94; Ex. H, [REDACTED]

[REDACTED]

In sum, the Court should adopt Plaintiffs’ proposed construction of “total lipid fraction,” which is consistent with the plain and ordinary meaning of the term, and reject Aker’s unduly narrow construction that is not supported by appropriate evidence.

2. Aker’s Process Extracts A Total Lipid Fraction Under Any Reasonable Definition

[REDACTED]

[REDACTED]

[REDACTED]

⁹ While Neptune does not believe this statement to be limiting at all, at most, it would require that to the extent that source material contains the listed classes of lipids, those *classes* must be represented in the “total lipid fraction” extracted.

[REDACTED]

[REDACTED]

[REDACTED] Indeed, in Aker's marketing materials and public statements, it repeatedly represents that its krill oil is a full extraction of the oil contained in the krill. SAF ¶ 97. Aker cannot tout the completeness of its krill oil to the industry, and then argue to this Court that its process does not extract the totality of the krill oil contained in the krill.

Moreover, even if this Court were to assume that the term must require each and every class of lipid contained in the source material to be present in the "total lipid fraction," Aker infringes. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Therefore, under any legitimate definition of the term "total lipid fraction," Aker's krill oil would meet that limitation of the claim.

E. Aker's Refusal to Produce Certain Relevant Documents and Things Precludes Entry of Summary Judgment

Aker has produced documents and testimony that it claims show it does not infringe the '299 patent. However, these documents and testimony simply cannot be reconciled with Plaintiffs' testing, which has [REDACTED] revealed the presence of acetone in Aker's products. Significant holes remain in the discovery provided by Aker that might help explain this inconsistency; Neptune ought to be permitted to obtain this missing discovery in order to

determine conclusively whether or not Aker is using acetone at any stage of its processing of Superba Krill Oil. In particular, the following are especially relevant:¹⁰

- Samples that represent all raw materials and substances involved in Aker's manufacture of its krill oil products. These include [REDACTED]
[REDACTED]
[REDACTED] The contents of these samples are relevant to Defendants' infringement, because to the extent that certain substances or solvents are present in them, that is key evidence relating to the methods that Defendants use.
- [REDACTED]
- [REDACTED]
- [REDACTED]

Aker's continuing refusal to provide this highly relevant information, when viewed in light of Neptune's test results, could support an inference that Aker is intentionally withholding information about the source of the acetone in its products. Therefore, Aker's refusal to produce this additional information ought to preclude entry of summary judgment. *Resolution Trust Corp., v. North Bridge Associates, Inc., et al.*, 22 F.3d 1198, 1208 (1st Cir. 1994) (reversing denial of Rule 56(f) motion and holding that "[w]hen Rule 56(f) functions properly, it ensures that...a litigant who fails to answer potentially relevant discovery requests on schedule will be unable to demand summary judgment until after he remedies his failure"). At a minimum, the Court should afford Neptune an opportunity to discover this information and defer decision on Aker's motion should be deferred until such discovery has been completed.

¹⁰ These documents and things are also the subject of Neptune's Motion Under Rule 56(d).

IV. Conclusion

For the reasons set forth above, the Court should deny Aker' motion for summary judgment of non-infringement.

Respectfully submitted,

/s/ Vinita Ferrera

Mark G. Matuschak

Hollie L. Baker

Vinita Ferrera

Jason H. Liss

WILMER CUTLER PICKERING HALE AND DORR LLP

60 State Street

Boston, MA 02109

(617) 526-6000

Sadaf R. Abdullah

WILMER CUTLER PICKERING HALE AND DORR LLP

399 Park Avenue

New York, NY 10022

(212) 230-8000

Jacob Oylo

WILMER CUTLER PICKERING HALE AND DORR LLP

1875 Pennsylvania Avenue, NW

Washington, DC 20006

(202) 663-6000

*Attorneys for Plaintiffs Neptune Technologies &
Bioresources, Inc. and L'Universite de Sherbrooke*

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/s/ Jason H. Liss

Jason H. Liss